UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

IN RE: VIAGRA (SILDENAFIL CITRATE) PRODUCTS LIABILITY LITIGATION	Case No. 3:16-md-02691-RS MDL No. 2691
This Document Relates to: ALL ACTIONS	**[~~JOINT PROPOSED~~] PRETRIAL ORDER No. 6 : DISCOVERY AND OTHER PROCEEDINGS RELATING TO GENERAL CAUSATION**

I. SCOPE OF ORDER

1. **Application and Purpose of Order.** This Order is intended to conserve judicial resources, eliminate duplicative discovery, serve the convenience of the parties and witnesses, and promote the just and efficient conduct of this litigation. This Order shall apply to all cases transferred to this Court by the Judicial Panel on Multidistrict Litigation ("JPML") pursuant to its Order of April 7, 2016, any tag-along actions transferred to this Court by the JPML, and any related actions that have been or will be originally filed in, transferred to, or removed to this Court and assigned thereto as part of *In re: Viagra (Sildenafil Citrate) Products Liability Litigation*, MDL No. 2691. This Order also may apply to state court actions, provided that the parties thereto so agree or the applicable court so orders. Plaintiffs' State/Federal Liaison Counsel agrees that he will support this Order being entered in any proceeding involving Viagra and/or Revatio in state court, including in the present action(s) in Missouri. This Order shall not be construed to affect the governing law or choice of law rules in any case subject to the Order.

2. **Scope of Discovery.** This Order relates to discovery and other proceedings concerning general causation. For purposes of this Order, the term "General Causation" refers to discovery related to causation issues of general or widespread applicability (*i.e.*, issues that are not specific to an individual Plaintiff). No party subject to the Order may serve any discovery not expressly authorized by the Order absent further Order of this Court or express agreement of the

parties. This provision shall not preclude third party discovery; provided, however, that any party intending to serve such third party discovery shall give ten (10) days written notice to the other party of the proposed third party discovery. Further, this Order shall not preclude the parties from conducting non-general causation discovery, if needed, after the Court enters its ruling on General Causation and after meeting and conferring about the scope of such discovery. By December 15, 2017, the parties will by separate proposed Order provide the Court a proposed Discovery Plan and Proposed Schedule for the selection of cases to be included in a discovery pool and for bellwether trials and selection.

3. **Use of Discovery in Federal and State Courts.** Discovery conducted pursuant to this Order may be utilized in state or federal court, in accordance with the applicable laws and rules of discovery and evidence. This provision shall not preclude any party from asserting in any action that any document, testimony, or other discovery produced pursuant to this Order is inadmissible at trial.

II. WRITTEN DISCOVERY

4. **Waiver of Initial Disclosures.** For all cases subject to this Order, the parties are relieved from complying with the requirements of Federal Rule of Civil Procedure 26(a) or any similar state court rule.

5. **Master Written Discovery by Plaintiffs.** Plaintiffs may serve on Pfizer the following written discovery related to General Causation: (1) Master Set(s) of Requests for Production (not to exceed fifty (50) requests for production, except by leave of this Court upon good cause shown); (2) Master Set(s) of Interrogatories (not to exceed twenty-five (25) interrogatories, including all discrete subparts, except by leave of this Court upon good cause shown); and (3) Master Set(s) of Requests for Admission.

6. **Master Written Discovery by Pfizer.** Pfizer may serve on the Plaintiffs' Steering Committee ("PSC"), to answer on behalf of all Plaintiffs, the following written discovery related to General Causation: (1) Master Request(s) for Production (not to exceed fifty (50) requests for production, except by leave of this Court upon good cause shown); (2) Master Set(s) of

Interrogatories (not to exceed twenty-five (25) interrogatories, including all discrete subparts, except by leave of this Court upon good cause shown); and (3) Master Set(s) of Requests for Admission.

7. **Additional Written Discovery.** Absent leave of Court, or by agreement of the parties, and subject to paragraph 2 above, no party may propound discovery on a party other than these Master Set(s) of Production, Master Set(s) of Interrogatories, and Master Set(s) of Requests for Admission.

III. PFIZER'S PRODUCTION OF DOCUMENTS

8. **Pfizer's Production of Non-Custodial Documents.** Pfizer shall produce (or where the parties agree it is appropriate, make available for review and/or inspection) to Plaintiffs a common set of non-custodial documents related to General Causation as follows:

a. **U.S. Regulatory Files and List of Clinical Trials.** Within two days of the parties' submission of a Joint Proposed Protective Order,[1] Pfizer shall produce: (1) its FDA regulatory files for Viagra and Revatio; and (2) a list of clinical trials for Viagra and for Revatio. With respect to preclinical trials of Viagra or Revatio, Plaintiffs shall provide a list of the preclinical trials as to which they may seek additional information. With respect to preclinical and clinical trials, the parties shall meet and confer with regard to what additional material Pfizer shall produce with respect to any of the trials, and a timetable for any such production.

b. **European Regulatory Documents and Adverse Event Reports.** On or before August 31, 2016, Pfizer shall produce: (1) its EMA regulatory file for Viagra and for Revatio; and (2) adverse event reports regarding Viagra and Revatio coded under the High Level Group Term ("HLGT") "Skin Neoplasm Malignant and Unspecified."

c. **Terminal Date.** The terminal date for the initial document production under the immediately preceding subparagraphs a. and b. shall be April 30, 2016. If after that time Pfizer communicates with or receives communications from FDA or EMA regarding Viagra

[1] For the convenience of the Court and the litigants, the deadlines contained in this Order are listed in an appendix at the end of the Order.

and/or Revatio with respect to skin neoplasms, skin cancer, and/or melanoma (except for adverse event reporting) Pfizer will supplement its production as to these issues. The parties will meet and confer regarding the scope and timing of such supplementation.

9. **Pfizer's Production of Custodial Documents Specifically Relating to Viagra and Revatio Only.** Pfizer shall produce custodial documents of ten (10) custodians, absent agreement of the parties. Plaintiffs shall have the right to request additional custodial files upon a showing of good cause after meeting and conferring with Pfizer. Plaintiffs shall identify the ten (10) custodians for whom Pfizer shall produce documents on or before October 31, 2016. Pfizer shall produce the custodial documents on a rolling basis, and complete production of all custodial documents on or before February 20, 2017. The terminal date for the initial production of custodial documents shall be April 30, 2016. Pfizer shall make any agreed supplemental production of custodial files on or before February 20, 2017. The parties will meet and confer regarding the date for any subsequent supplemental production.

10. **Assertion of Privilege and Privilege Logs.** Any party that withholds and/or redacts the production of requested documents or materials on the ground of any privilege or application of the work-product doctrine must provide a Privilege Log. Each Privilege Log shall describe each document or thing for which a privilege or the work-product doctrine is asserted in sufficient detail to reasonably permit the party seeking discovery to assess whether or not to dispute any such assertion of privilege or application of the work-product doctrine. This will include but is not limited to information regarding the document's subject, date, author, and all recipients, the specific privilege asserted, and the factual basis for the privilege. Each party withholding materials shall provide opposing counsel a copy of the Privilege Log in electronic form contemporaneously with each production whenever possible, and no later than sixty (60) days after the production absent agreement of the parties. The parties shall not be required to log communications with outside counsel that occurred after January 1, 2015. The parties shall produce responsive, non-privileged attachments to privileged documents.

IV. DEPOSITIONS

11. **Number of Depositions.** Plaintiffs may take no more than seven (7) depositions of Pfizer fact witnesses (whether currently or formerly employed by Pfizer), absent agreement of the parties or good cause shown by Plaintiffs. This limitation does not include any depositions relating to ESI/document preservation and/or corporate structure conducted pursuant to Federal Rule of Civil Procedure 30(b)(6) or any comparable state rule of civil procedure.

12. **Completion of Depositions.** Depositions of Pfizer fact witnesses shall be completed by August 30, 2017.

13. **Deposition Notices.** A single deposition notice shall apply in all cases governed by this Order. Pfizer agrees to cross-notice all depositions.

a. **Deposition Scheduling.** Depositions must be noticed pursuant to Federal Rule of Civil Procedure 30 at least thirty (30) calendar days in advance, with notice served upon counsel. Absent extraordinary circumstances, counsel shall consult with opposing counsel and proposed deponents in advance in an effort to schedule depositions at mutually convenient times and places. Depositions should be scheduled by agreement of the parties based upon the availability of documents relevant to the specific witness and the availability of the witness and counsel. No more than one (1) deposition may be scheduled on the same day. Absent leave of court, no Pfizer fact witnesses may be deposed more than once.

b. **Deposition Week.** In any week in which depositions will be taken, such depositions shall commence no earlier than 9:30 a.m. on Monday and end no later than 3:00 p.m. on Friday of that week, unless by agreement of the parties or court order.

c. **Deposition Day.** Except as stated above, the deposition day shall commence at 9:30 a.m. unless by agreement of the parties or court order.

d. **Deposition Length.** All depositions shall be limited to seven hours of examination by the noticing side, absent good cause shown or agreement of the parties. Examination by the non-noticing side shall not count against the seven-hour limit. The parties shall endeavor to limit duplicative questioning so as to be as efficient as possible with respect to

deposition time. If Lead Counsel for either side believes that the deposition will or may last beyond one day, Lead Counsel shall notify opposing Lead Counsel at the time of issuing the deposition notice or within a reasonable time thereafter, so that the parties may meet and confer with respect to whether any additional deposition time is warranted and schedule the deposition accordingly. Consent to additional deposition time shall not be unreasonably withheld. Absent exceptional circumstances or agreement of the parties, neither side may obtain additional deposition time if they do not request the additional time at the time of issuing the deposition notice or within a reasonable time thereafter.

e. **Locations for Taking Depositions.** Unless otherwise agreed by counsel for Pfizer, depositions of Pfizer fact witnesses (current and former employees) will take place in one of the following locations, as designated by Pfizer: DLA Piper's offices in New York, NY, Williams & Connolly LLP's or DLA Piper's offices in Washington, D.C., and other locations as designated by Williams & Connolly LLP and/or DLA Piper.

14. **Other Deposition Logistics.**

a. **Attendance at Depositions.** Unless otherwise agreed by the parties, depositions may be attended only by the parties, the deponent, the deponent's attorney, attorneys representing any party in any action governed by this Order (including any employee or retained consultant of such attorney who is assisting in the litigation and whose presence is reasonably required by the attorney), in-house counsel for Pfizer, the court reporter, and the videographer.

b. **Sequence of Examination.** Questioning at the depositions will be conducted in the following sequence: (1) examination by one attorney designated by MDL Plaintiffs' Lead Counsel; (2) examination by up to two attorneys designated by the Federal/State Liaison Counsel; (3) examination by Plaintiffs' counsel in any other state court litigations, provided that such counsel do not exceed one counsel per state and the deposition was properly cross-noticed; (4) examination by one attorney designated by Pfizer's Lead Counsel; (5) any physician or healthcare provider's counsel, provided that such counsel do not exceed one counsel per state; (6) examination by individual counsel for the deponent, if any, other than counsel

above; and (7) any re-examination by the counsel listed above, provided that time remains within the Plaintiffs' seven-hour limit. Plaintiffs' counsel shall cooperate with respect to the division of time so as to ensure that the interests of the state court Plaintiffs' counsel are adequately addressed, and the Plaintiffs' attorneys designated to conduct the examinations shall coordinate with each other so as to conduct as thorough and non-duplicative an examination as is practicable. The parties shall leave sufficient time for examination by the attorney designated by Pfizer's Lead Counsel, any physician or healthcare provider's counsel, and examination by individual counsel for the deponent, but such time shall not count against the Plaintiffs' seven hours.

c. **Objections at Depositions.** All objections as to relevance and admissibility (*i.e.*, objections other than to the form of the question) shall be preserved for later ruling by the court in which the action is pending. As soon as any one attorney representing a party to this litigation states the word "objection," all parties shall be deemed to have preserved all possible objections to the form of the question or the responsiveness of the answer. Counsel for other parties shall not repeat the objection.

15. **Deposition Exhibits.**

a. **Use of Confidential Documents.** While a deponent is being examined about any document that is confidential (or highly confidential, or otherwise subject to designation under the terms of the Protective Order entered in this litigation) because (1) the parties have so agreed, (2) a party has designated the document confidential (or highly confidential, or otherwise designated the document) under the terms of the Protective Order, or (3) a Court has so ordered, attendance at that deposition by persons to whom disclosure is not authorized by agreement of the parties, the terms of the Protective Order, or by court order shall be prohibited. Any portion of the deposition transcript containing confidential information (or highly confidential information or information otherwise subject to the Protective Order) shall be sealed as set forth in the Protective Order. Sealed portions of deposition transcripts may be opened, read, and utilized for all purposes as permitted by the terms of the Protective Order entered in this litigation.

b. **Provision of Hard Copies.** Extra hard copies of documents about which counsel expect to examine the deponent should be provided to the reporter, the deponent, deponent's counsel, and a reasonable number of copies for counsel for the other party participants during the deposition.

c. **Use of Bates Numbers.** To the extent possible, all exhibits shall have printed Bates numbers affixed. Documents that have not been previously produced shall be assigned a Bates number from a range of numbers reserved for this purpose. The first time a document is marked as a deposition exhibit, it shall be referred to by the Bates number appearing on the document.

d. **Marking of Deposition Exhibits.** All documents marked as exhibits shall be attached to the original transcript and retained with the original transcript. Copies of exhibits may be attached to copies of the transcript where the party ordering the transcript pays for the costs of copying those exhibits.

16. **Videotaped Depositions.** The provisions of this Order regarding examination of deponents apply to videotaped depositions. Any deposition may be videotaped at the request of a party pursuant to the following terms and conditions:

a. **Stenographic Recording.** A certified court reporter shall simultaneously record stenographically all deposition proceedings and testimony. The court reporter shall administer the oath or affirmation to the deponent on camera. The written transcript by the court reporter shall constitute the official record of the deposition for purposes of Federal Rule of Civil Procedure 30(e) (submission to the witness) and 30(f) (filing; exhibits).

b. **Cost of Deposition.** The noticing party shall bear the expense of videotaping and stenographic recording. Motions to recover these costs and expenses may be made at the conclusion of the litigation in accordance with applicable law.

c. **Videotape Operator.** The video camera shall be operated by an experienced video camera operator ("videotape operator"). The videotape operator shall be subject to the provisions of Federal Rule of Civil Procedure 28(c). The videotape operator shall not distort the

appearance or the demeanor of participants in the deposition by the use of camera or sound recording techniques.

d. **Interruptions.** The video camera operation will be suspended during the deposition only by agreement of counsel examining and defending the deposition, and "off the record" discussions shall not be videotape recorded. The video camera operator shall record on camera the time of suspension and any subsequent reconvening of the deposition.

e. **Index.** The videotape operator shall use a counter on the recording equipment and after completion of the deposition shall prepare a log, cross-referenced to counter numbers, that identifies the positions on the tape at which examination by different counsel begins and ends, at which objections are made and examination resumes, at which exhibits are identified, and at which any interruption of continuous tape recording occurs, whether for recesses, "off the record" discussion, mechanical failure, or otherwise.

f. **Certification.** After the deposition is completed, the video operator shall certify on camera the correctness, completeness, and accuracy of the videotape recording in the same manner as a stenographic court reporter.

g. **Technical Data.** Technical data, such as recording speeds and other information needed to replay or copy the tape, shall be included with copies of the videotapes.

h. **Exhibits.** If examining counsel uses an Elmo or other device to capture document images during a videotaped deposition and incorporate the image into the videotape, such counsel may highlight or underline portions of the document but may not otherwise manipulate the document, such as by writing on or otherwise altering the document.

i. **No Distortion.** The camera operators shall not distort the appearance or the demeanor of participants in the deposition by the use of camera or sound recording techniques.

17. **Deposition Transcripts.**

a. **Services of Deposition Officer.** Services and products offered or provided by a deposition officer (i.e., a court reporter or videotape operator) or the entity providing the

services of a deposition officer to any party or to any party's attorney or non-party who is financing all or part of the deposition shall be offered or provided to all parties or their attorneys attending the deposition.

b. **Real-Time Transcription.** Any party may arrange for "real-time" transcription of a deposition at its own cost.

c. **Correction and Signing of Deposition.** The transcript of a deposition shall be submitted to the deponent for correction and signature within sixty (60) days after receipt of the transcript from the court reporter. The deposition may be signed by the deponent before any notary or pursuant to 28 U.S.C. § 1746. If no corrections are made within sixty (60) days after receipt of the certified transcript from the deposition officer, the transcript will be deemed accurate and the parties shall have the right to use a copy of the transcript in any further proceedings as though the copy were the original transcript. In the event the original transcript is unsigned, lost, stolen, or inadvertently destroyed, a certified copy reflecting any changes made to the original transcript may be used in place of the original.

V. EXPERT DISCOVERY

18. **Expert Reports and Depositions.** For purposes of the schedule set forth in this Order, each party may designate no more than six (6) General Causation Experts. The designation of General Causation Experts must be accompanied by a report that complies with Federal Rule of Civil Procedure 26(a)(2)(B), which must be provided contemporaneously with the expert designation. The experts shall be subject to deposition as directed in Federal Rule of Civil Procedure 26(b)(4)(A) on the schedule provided below. This Order shall not preclude the parties from designating additional experts who may offer opinions relating to General Causation after the resolution of the General Causation *Daubert* motions referenced below; provided, however, that no party may designate an expert to offer any opinion that the Court has ruled inadmissible.

19. **Production and Discoverability of Expert Materials.** Each expert will produce his or her final report and a list of all documents that the expert considered in preparing and/or

rendering the expert's opinion. No other documents relating to expert reports will be produced; provided, however, that nothing in this agreement is intended to bar discovery of documents that are otherwise discoverable from a party or third party outside of the context of expert discovery. No party will seek discovery of any experts' notes, drafts of expert reports, or communications with counsel; provided, however, that counsel may inquire at deposition about any facts provided to the expert by counsel and upon which such expert is relying in expressing the expert's opinions.

20. **Designation and Depositions of Experts.** The parties shall designate and depose experts as follows:

a. **Plaintiffs' Designations.** Plaintiffs shall designate General Causation Experts on or before October 3, 2017.

b. **Pfizer's Designations.** Pfizer shall designate General Causation Experts on or before November 15, 2017.

c. **Depositions of General Causation Experts.** Depositions of Plaintiffs' General Causation Experts may commence on December 1, 2017. Absent agreement of the parties, depositions of Pfizer's General Causation Experts may commence after the completion of depositions of Plaintiffs' General Causation Experts. All depositions of General Causation Experts shall be completed by March 30, 2018.

21. **Motions Relating to General Causation.** Any *Daubert* or other motion directed to general causation issues must be filed by April 30, 2018. Oppositions to such motions must be filed by May 29, 2018, and any reply briefs must be filed by June 29, 2018.

IT IS SO ORDERED.

Dated: 9/26/16

THE HONORABLE RICHARD SEEBORG
UNITED STATES DISTRICT JUDGE

APPENDIX – LIST OF DEADLINES

Deadline	Task
Within 2 days of the parties' submission of a Joint Proposed Protective Order	Pfizer to produce: (1) FDA regulatory files for Viagra and Revatio; (2) list of clinical trials for Viagra and Revatio; and (3) Pfizer's submission to EMA PRAC and PRAC's PAR
August 31, 2016	Pfizer to produce: (1) remainder of EMA regulatory files for Viagra and Revatio; and (2) certain adverse event reports regarding Viagra and Revatio
October 31, 2016	Plaintiffs to identify custodians for whom Pfizer shall produce documents
February 20, 2017	Pfizer to complete custodial document production
August 30, 2017	Depositions of Pfizer fact witnesses to be completed
October 3, 2017	Plaintiffs to designate General Causation Experts and produce Expert Reports
November 15, 2017	Pfizer to designate General Causation Experts and produce Expert Reports
December 1, 2017	Depositions of Plaintiffs' General Causation Experts may commence; depositions of Pfizer's General Causation Experts may commence after completion of depositions of Plaintiffs' General Causation Experts
March 30, 2018	All depositions of General Causation Experts to be completed
April 30, 2018	Deadline for filing *Daubert* or other motions directed to General Causation issues
May 29, 2018	Deadline for filing oppositions to General Causation motions
June 29, 2018	Deadline for filing reply briefs in support of *Daubert* or other motions directed to General Causation issues